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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,772	12/29/2003	Rafael A. Fissore	60141.0036usu1	6476
7590 04/11/2006 Merchant & Gould P.C. P.O. Box 2903 Minneapolis, MN 55402-0903			EXAMINER PARAS JR, PETER	
			ART UNIT	PAPER NUMBER

1632

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/747,772	Applicant(s) FISSORE ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 11, 13, 18-21, 24 and 26-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 14-17, 22, 23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9102004, 2252005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-60 are pending.

Election/Restrictions

Applicant's election of Group I, claims 1-9, 12, 14-17, 22-23 and 25 in the reply filed on 1/12/06 is acknowledged; claim 10 is a linking claim and is also under current consideration. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11, 13, 18-21, 24 and 26-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/12/06.

Claims 1-10, 12, 14-17, 22-23 and 25 are under current consideration.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See for example at page 16, at line 30.

Appropriate correction is required.

Claim Objections

Claims 1-10, 12, 14-17, 22-23 and 25 are objected to because of the following informalities: the claims embrace non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12, 14-17, 22-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention features a method for activation of oocytes. The method comprises introduction of a spermatocyte into an oocyte and then removing the spermatocyte from the oocyte after a sufficient amount of time. The specification asserts that such a method will result in activation of an oocyte to produce an embryo by parthenogenesis. The elected invention is directed to embrace production of a naturally occurring embryo, which is interpreted to mean natural union of a sperm and oocyte *in vivo*; the claimed method is to be practiced *in vivo*. While the specification has provided guidance correlating introduction and removal of mouse sperm from a mouse

oocyte *in vitro*, resulting in activation of a mouse oocyte, the specification has failed to provide any guidance correlating to introduction and removal of sperm from an oocyte *in vivo*. Moreover, the conditions and parameters for practicing the claimed methods are not apparent from the lack of guidance provided by the specification. Therefore, it would be unpredictable if the methods could be practiced *in vivo*. Given, the lack of guidance provided by the specification it would have required undue experimentation for one of skill in the art to practice the invention *in vivo* without a reasonable expectation of success.

As a first issue, the elected invention is directed to embrace a naturally occurring embryo. Although the steps of the method embrace culturing, naturally occurring is interpreted to embrace *in vivo* introduction (fertilization) of a sperm into an oocyte (to create an embryo). Moreover, the specification has asserted that embryonic development is to occur by parthenogenesis upon removal of sperm. In such a scenario, parthenogenesis is induced by hand of man (artificial removal of sperm) and would not be considered naturally occurring. In any event, the specification has failed to provide guidance for practicing the claimed methods under conditions that result in a naturally occurring embryo. The conditions and parameters for fertilization and subsequent removal of sperm from an oocyte *in vivo* are not apparent given the lack of guidance provided by the specification. For example, the specification has not provided guidance correlating to removal of sperm from an oocyte *in vivo*. In order to practice the method *in vivo*, it would require knowledge of where the fertilized oocytes would at around the time fertilization (for all species embraced by the claims). Moreover,

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practice of the method would also require technology for removing the sperm from the oocyte *in vivo*. The specification has not provided any guidance correlating to removal of sperm from an oocyte *in vivo*, which would result in a naturally occurring embryo. The state of the art is silent with respect to such technology. Therefore, one of skill in the art would be left to speculate how sperm would be removed from an oocyte *in vivo*; this technology appears to be undeveloped at best. In light of the above, it would be unpredictable if sperm could be removed from an oocyte *in vivo* and result in creation of a naturally occurring embryo.

In addition, the breadth of the claims embraces sperm and cells (oocytes) from all species of animals. Moreover, since the elected invention is directed to embrace creation of a naturally occurring embryo *in vivo*, it would be unpredictable if sperm from a given species would fertilize an oocyte from a different species *in vivo*, particularly since this appears to require mating between different species of animals; the specification has failed to provide guidance to that end. In the event that cross breeding between different species of mammals were possible, it is unpredictable if viable offspring would result. See Fehilly et al (Nature, 1984, 307: 634-636). Given the lack of guidance provided by the specification it would have required undue experimentation for one of skill in the art to make and use the invention as claimed without a reasonable expectation of success.

As a final issue, the breadth of the claims embraces introduction of sperm into any mammalian cell, including cells of an embryo. The specification and the state of the art have taught that sperm must be introduced into an oocyte to practice the claimed

methods. The oocyte becomes activated, upon introduction of the sperm, and via parthenogenesis develops into an embryo. It would be unpredictable if any cell, other than an oocyte, could develop into an embryo via parthenogenesis. Given the lack of guidance provided by the specification it would have required undue experimentation to make and use the invention as claimed with any mammalian cell without a reasonable expectation of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12, 14-17, 22-23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 are indefinite as written. The claim embraces culturing a cell. However, the elected invention is directed to embrace creation of a naturally occurring embryo. Naturally occurring embryo is interpreted to read on an embryo in vivo. Therefore, it is not understood how a naturally occurring embryo, in vivo, is cultured. Appropriate correction is required. Claims 2-10, 12, 14-17, 22-23 and 25 depend from claim 1.

Claim 10 recites the limitation "the embryo" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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Claims 16 and 25 are indefinite as written. The claims embrace a cell that comprises an oocyte or an embryo. It is not understood how a cell can comprise an embryo or even an oocyte. A cell can be an oocyte. An embryo comprises a cell. Appropriate correction is required. Claims 22-23 depend from claim 16.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Paras, Jr. whose telephone number is 571-272-4517. The examiner can normally be reached on M-Th, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

**PETER PARAS, JR.
PRIMARY EXAMINER**

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A handwritten signature in black ink, appearing to read "Peter Paras", is written below the printed name and title.